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Subpart A—General Information

§ 285.1 Purpose.

The purpose of part 285 is to set out procedures and general requirements under which the National Voluntary Laboratory Accreditation Program (NVLAP) operates to accredit both calibration laboratories and testing laboratories in response to:

(a) Mandates by the Federal government through legislative or administrative action;

(b) Requests from a government agency (§ 285.13); and

(c) Requests from a private sector organization (§ 285.14).

Supplementary technical and administrative requirements are provided in supporting handbooks and documents as needed depending on the criteria established for specific Laboratory Accreditation Programs (LAPs).

§ 285.2 Organization of procedures.

Subpart A describes considerations which relate in general to all aspects of NVLAP. Subpart B describes how new LAPs are requested, developed, and announced, and how LAPs are terminated. Subpart C describes procedures for accrediting laboratories. Subpart D sets out the conditions and criteria for NVLAP accreditation.

§ 285.3 Description and goal of NVLAP.

(a) NVLAP is a system for accrediting calibration laboratories and testing laboratories found competent to perform specific tests or calibrations. Competence is defined as the ability of a laboratory to meet the NVLAP conditions (§ 285.32) and to conform to the criteria (§ 285.33) in NVLAP publications for specific calibration and test methods.

(b) NVLAP is a process which:

(1) Provides the technical and administrative mechanisms for national and international recognition for competent laboratories based on a comprehensive procedure for promoting confidence in calibration and testing laboratories that show that they operate in accordance with NVLAPs requirements;

(2) Provides laboratory management with documentation for use in the development and implementation of their quality systems;

(3) Identifies competent laboratories for use by regulatory agencies, purchasing authorities, and product certification systems;

(4) Provides laboratories with guidance from technical experts to aid them in reaching a higher level of performance resulting in the generation of improved engineering and product information; and

(5) Promotes the acceptance of calibration and test results between countries, and facilitates cooperation between laboratories and other bodies to assist in the exchange of information and experience, facilitating removal of non-tariff barriers to trade and promoting the harmonization of standards and procedures.

(c) NVLAP is comprised of a series of laboratory accreditation programs (LAPs) which are established on the basis of requests and demonstrated need. The specific calibration and test methods, types of calibration and test methods, products, services, or standards to be included in a LAP are determined by an open process during the establishment of the LAP (see § 285.11). The Chief of NVLAP does not unilaterally propose or decide the scope of a LAP. Communication with other laboratory accreditation systems is fostered to encourage development of common criteria and approaches to accreditation and to promote the domestic, foreign, and international acceptance of test data produced by the accredited laboratories.

[49 FR 44623, Nov. 8, 1984. Redesignated at 59 FR 22745, May 3, 1994, as amended at 64 FR 59617, Nov. 3, 1999]

§ 285.4 References.

NVLAP is designed to be compatible with domestic and foreign laboratory accreditation programs to ensure the universal acceptance of test data produced by NVLAP-accredited laboratories. In this regard, these Procedures are compatible with:

(a) The most recent official publications of ISO Guides 2, 25, 30, 38, 43, 45, 49, 58, and Standards 8402, 9001, 9002, 9003, and 9004.

(b) International vocabulary of basic and general terms in metrology (VIM) and Guide to the expression of uncertainty in measurement, issued by International Bureau of Weights and Measures (BIPM), International Electrotechnical Commission (IEC), International Federation of Clinical Chemistry (IFCC), International Organization for Standardization (ISO), International Union of Pure and Applied Chemistry (IUPAC), International Union of Pure and Applied Physics (IUPAP), and International Organization of Legal Metrology (OIML).

§ 285.5 Definitions.

Accreditation (of a laboratory): A formal recognition that a laboratory is competent to carry out specific tests or calibrations or types of test or calibrations.

Accreditation criteria: A set of requirements used by an accrediting body which a laboratory must meet in order to be accredited.

Approved Signatory (of an accredited laboratory): An individual who is recognized by NVLAP as competent to sign accredited laboratory calibration or test reports.

Assessment (of a laboratory): The onsite examination of a testing or calibration laboratory to evaluate its compliance with the conditions and criteria for accreditation.

Authorized Representative (of an accredited laboratory): An individual who is authorized by the laboratory or the parent organization to sign the NVLAP application form and commit the laboratory to fulfill the NVLAP requirements (The Authorized Representative may also be recommended by the laboratory as an Approved Signatory).

Calibration: A set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or system, or values represented by a material measure, and the corresponding known values of a measurand.

Calibration method: A defined technical procedure for performing a calibration.

Certificate of Accreditation: A document issued by NVLAP to a laboratory that has met the criteria and conditions for accreditation. The Certificate of Accreditation may be used as proof of accredited status. A Certificate of Accreditation is always accompanied with a Scope of Accreditation.

Competence: The ability of a laboratory to meet the NVLAP conditions and to conform to the criteria in NVLAP publications for specific calibration and test methods.

Deficiency: The non-fulfillment of NVLAP conditions and/or criteria for accreditation.

Director of NIST: The Director of the National Institute of Standards and Technology or designate.

Laboratory: An organization that performs calibrations and/or tests. When a laboratory is part of an organization that carries out activities additional to calibration and testing, the term ''laboratory'' refers only to those parts of that organization that are involved in the calibration and testing process. The laboratory activities may be carried out at or from a permanent location, at or from a temporary facility, or in or from a mobile facility.

LAP: A laboratory accreditation program established and administered under NVLAP, consisting of test methods or calibrations relating to specific products or fields of testing or calibration.

NIST: The National Institute of Standards and Technology.

NVLAP: The National Voluntary Laboratory Accreditation Program. NVLAP is an Office within the National Institute of Standards and Technology.

Person: Associations, companies, corporations, educational institutions, firms, government agencies at the federal, state and local level, partnerships, and societies—as well as divisions thereof—and individuals.

Product: A type or a category of manufactured goods, constructions, installations, and natural and processed materials, or those associated services whose characterization, classification, or functional performance is specified by standards or test methods.

Proficiency testing: The determination of laboratory performance by means of